

cell disorders, such as iron deficiency anemia.

(b) *Classification*. Class II (performance standards).

§ 866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

(a) *Identification*. An inter-*alpha* trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-*alpha* trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

Subpart G—Tumor Associated Antigen Immunological Test Systems

§ 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification*. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification*. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,” and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

§ 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) *Identification*. An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) *Classification*. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.” See § 866.1(e) for availability of this guidance document.

[69 FR 26038, May 11, 2004]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

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868.1 Scope.

868.3 Effective dates of requirement for premarket approval.

868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

868.1030 Manual algesimeter.

868.1040 Powered algesimeter.

868.1075 Argon gas analyzer.

868.1100 Arterial blood sampling kit.

868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.

868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.

868.1400 Carbon dioxide gas analyzer.

868.1430 Carbon monoxide gas analyzer.

868.1500 Enflurane gas analyzer.

868.1575 Gas collection vessel.

868.1620 Halothane gas analyzer.

868.1640 Helium gas analyzer.

868.1670 Neon gas analyzer.

868.1690 Nitrogen gas analyzer.

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868.1700 Nitrous oxide gas analyzer.
868.1720 Oxygen gas analyzer.
868.1730 Oxygen uptake computer.
868.1750 Pressure plethysmograph.
868.1760 Volume plethysmograph.
868.1780 Inspiratory airway pressure meter.
868.1800 Rhinoanemometer.
868.1840 Diagnostic spirometer.
868.1850 Monitoring spirometer.
868.1860 Peak-flow meter for spirometry.
868.1870 Gas volume calibrator.
868.1880 Pulmonary-function data calculator.
868.1890 Predictive pulmonary-function value calculator.
868.1900 Diagnostic pulmonary-function interpretation calculator.
868.1910 Esophageal stethoscope.
868.1920 Esophageal stethoscope with electrical conductors.
868.1930 Stethoscope head.
868.1965 Switching valve (ploss).
868.1975 Water vapor analyzer.

Subpart C—Monitoring Devices

868.2025 Ultrasonic air embolism monitor.
868.2300 Bourdon gauge flowmeter.
868.2320 Uncompensated thorpe tube flowmeter.
868.2340 Compensated thorpe tube flowmeter.
868.2350 Gas calibration flowmeter.
868.2375 Breathing frequency monitor.
868.2377 Apnea monitor.
868.2380 Nitric oxide analyzer.
868.2385 Nitrogen dioxide analyzer.
868.2450 Lung water monitor.
868.2480 Cutaneous carbon dioxide (PcCO_2) monitor.
868.2500 Cutaneous oxygen (PcO_2) monitor.
868.2550 Pneumotachometer.
868.2600 Airway pressure monitor.
868.2610 Gas pressure gauge.
868.2620 Gas pressure calibrator.
868.2700 Pressure regulator.
868.2775 Electrical peripheral nerve stimulator.
868.2875 Differential pressure transducer.
868.2885 Gas flow transducer.
868.2900 Gas pressure transducer.

Subparts D–E [Reserved]**Subpart F—Therapeutic Devices**

868.5090 Emergency airway needle.
868.5100 Nasopharyngeal airway.
868.5110 Oropharyngeal airway.
868.5115 Device to relieve acute upper airway obstruction.
868.5120 Anesthesia conduction catheter.
868.5130 Anesthesia conduction filter.
868.5140 Anesthesia conduction kit.
868.5150 Anesthesia conduction needle.
868.5160 Gas machine for anesthesia or analgesia.

868.5165 Nitric oxide administration apparatus.
868.5170 Laryngotracheal topical anesthesia applicator.
868.5180 Rocking bed.
868.5220 Blow bottle.
868.5240 Anesthesia breathing circuit.
868.5250 Breathing circuit circulator.
868.5260 Breathing circuit bacterial filter.
868.5270 Breathing system heater.
868.5280 Breathing tube support.
868.5300 Carbon dioxide absorbent.
868.5310 Carbon dioxide absorber.
868.5320 Reservoir bag.
868.5330 Breathing gas mixer.
868.5340 Nasal oxygen cannula.
868.5350 Nasal oxygen catheter.
868.5365 Posture chair for cardiac or pulmonary treatment.
868.5375 Heat and moisture condenser (artificial nose).
868.5400 Electroanesthesia apparatus.
868.5420 Ether hook.
868.5430 Gas-scavenging apparatus.
868.5440 Portable oxygen generator.
868.5450 Respiratory gas humidifier.
868.5460 Therapeutic humidifier for home use.
868.5470 Hyperbaric chamber.
868.5530 Flexible laryngoscope.
868.5540 Rigid laryngoscope.
868.5550 Anesthetic gas mask.
868.5560 Gas mask head strap.
868.5570 Nonrebreathing mask.
868.5580 Oxygen mask.
868.5590 Scavenging mask.
868.5600 Venturi mask.
868.5610 Membrane lung for long-term pulmonary support.
868.5620 Breathing mouthpiece.
868.5630 Nebulizer.
868.5640 Medicinal nonventilatory nebulizer (atomizer).
868.5650 Esophageal obturator.
868.5655 Portable liquid oxygen unit.
868.5665 Powered percussor.
868.5675 Rebreathing device.
868.5690 Incentive spirometer.
868.5700 Nonpowered oxygen tent.
868.5710 Electrically powered oxygen tent.
868.5720 Bronchial tube.
868.5730 Tracheal tube.
868.5740 Tracheal/bronchial differential ventilation tube.
868.5750 Inflatable tracheal tube cuff.
868.5760 Cuff spreader.
868.5770 Tracheal tube fixation device.
868.5780 Tube introduction forceps.
868.5790 Tracheal tube stylet.
868.5795 Tracheal tube cleaning brush.
868.5800 Tracheostomy tube and tube cuff.
868.5810 Airway connector.
868.5820 Dental protector.
868.5830 Autotransfusion apparatus.
868.5860 Pressure tubing and accessories.
868.5870 Nonrebreathing valve.
868.5880 Anesthetic vaporizer.

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868.5895 Continuous ventilator.
868.5905 Noncontinuous ventilator (IPPB).
868.5915 Manual emergency ventilator.
868.5925 Powered emergency ventilator.
868.5935 External negative pressure ventilator.
868.5955 Intermittent mandatory ventilation attachment.
868.5965 Positive end expiratory pressure breathing attachment.
868.5975 Ventilator tubing.
868.5995 Tee drain (water trap).

Subpart G—Miscellaneous

868.6100 Anesthetic cabinet, table, or tray.
868.6175 Cardiopulmonary emergency cart.
868.6225 Nose clip.
868.6250 Portable air compressor.
868.6400 Calibration gas.
868.6700 Anesthesia stool.
868.6810 Tracheobronchial suction catheter.
868.6820 Patient position support.
868.6885 Medical gas yoke assembly.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 31142, July 16, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet

at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17734, May 11, 1987, as amended at 67 FR 76681, Dec. 13, 2002]

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section